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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/001,039	12/30/1997	DOUGLAS J. JOLLY	1155.005	6098

27476 7590 04/04/2002

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/001,039

## Applicant(s)

JOLLY ET AL.

## Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 4,5 and 37-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 37-56 is/are allowed.
- 6) ☐ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pensiero et al. in view of Mulligan et al. and Hermann et al.

Applicants claim a replication defective recombinant retroviral vector expressing human factor VIII protein wherein said vector is capable of infecting human cells and is resistant to inactivation by human complement and wherein said vector preparation has a titer on HT1080 cells of greater than  $10^6$  cfu/ml.

Pensiero et al. (U.S. Patent 6,329,199, issued 12/11/01, effective filing date 8/17/94, see whole document, particularly columns 5-6) recites a replication defective recombinant retroviral vector which can express human factor VIII and is capable of

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infecting human cells and is resistant to inactivation by human complement. Pensiero et al. does not recite retroviral vector preparations having a titer on HT1080 cells of greater than  $10^6$  cfu/ml.

Mulligan et al. (previously cited in the prior Office Action, see whole document, particularly columns 26-28) discloses the fact that cDNA for human factor VIII was known and human factor VIII sequences could be expressed in retroviral vectors.

Hermann et al. (previously cited in the prior Office Action, see whole document, particularly columns 8-9) discloses methods of preserving recombinant retroviral vector preparations such that high titer is maintained. Retrovirus preparations stored in the presence of saccharides were demonstrated to have titers on HT1080 cells of greater than  $10^6$  cfu/ml (Figs. 1-3).

The claimed invention is essentially taught by Pensiero et al. The secondary references to Mulligan et al. and Hermann et al. merely recite the well known human factor VIII gene and methods for maintaining high titers of retroviral vectors, respectively. One of ordinary skill in the art seeking to generate the claimed retroviral vector preparations would have been motivated to use the teachings of Pensiero et al. on the generation of recombinant replication defective retroviral vectors which are resistant to inactivation by human complement and which can express human factor VIII combined with the teachings of Mulligan et al. on the well known, cloned, human factor VIII gene and the teachings of Hermann et al. on storage of retroviral vectors to maintain high titers of greater than  $10^6$  cfu/ml on HT1080 cells in order to generate replication defective retroviral vectors capable of expressing human factor VIII and

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maintaining said vectors at high titers. It would have been obvious for the ordinary skilled artisan to do this because Pensiero et al. teaches the generation of replication defective retroviral vectors which can express the human factor VIII gene and the ordinary skilled artisan would have had access to the cloned human factor VIII coding sequence (Mulligan et al.) and to procedures for maintaining high titers of retroviral vectors on HT1080 cells (Hermann et al.) so that said artisan would have been able to generate the claimed retroviral vector preparations. Given the teachings of the cited prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 are vague in the recitation of the phrase "titer of HT1080 cells". Applicants appear to be claiming a titer of viruses **on** HT1080 cells because viruses are titered on cells; cells are not titered. Correction is required.

Claims 37-56 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo

April 1, 2002

DAVID GUZO  
PRIMARY EXAMINER  
